ST 00-0255-GIL 11/21/2000 MANUFACTURING MACHINERY & EQUIPMENT

Under the Retailers' Occupation Tax Act, the manufacturing machinery and equipment exemption extends to machinery and equipment that is used primarily (over 50% of the time) in the manufacturing or assembling of tangible personal property for wholesale or retail sale or lease. See 86 Ill. Adm. Code 130.330. (This is a GIL.)

November 21, 2000

Dear Xxxxx:

This letter is in response to your letter received September 19, 2000. The nature of your letter and the information you have provided require that we respond with a General Information Letter, which is designed to provide general information, is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120 subsections (b) and (c), which can be found at http://www.revenue.state.il.us/legalinformation/regs/part1200.

In your letter, you have stated and made inquiry as follows:

The Petitioner is engaged in plasmapheresis. While the process has historically been a manual operation, the process now utilizes the Haemonetics PSC Pheresis system. The process involves withdrawing whole blood from a previously screened human donor by the means of inserting a hollow needle into a vein in the arm and withdrawing a quantity of blood in a sterile plastic bag. The plasma is then separated in a centrifuge type operation by the Haemonetics machine into the liquid plasma, which is extracted. A small quantity of an anticoagulant solution is added to the red blood cells which following separation are reinjected into the body of the donor through the hollow needle. During the processing, the materials are maintained at a temperature not exceeding 37 degrees Centigrade. The Source Plasma is stored in pooling bags in refrigerated areas at –20 degrees Centigrade while awaiting test results. After test results are received, the Source Plasma is sold to pharmaceutical companies for further manufacturing into controlled substances.

The taxpayer's operations are conducted at its Illinois location and this operation is exclusively manufacturing Source Plasma. This manufacturing operation, commonly known as plasmapheresis, is strictly controlled, monitored and licensed by the Federal government through the F.D.A. and by the Department of Health of the State of Illinois.

Manufacturing does not always mean the transformation of raw materials into new articles in the mechanical sense. Manufacturing implies a change and consists of giving new shapes, new qualities or new combinations to matter. Manufacturing requires a transformation; a new and different article must emerge, having a distinctive name, character or use. The transformation must be in form, qualities and adaptability in use which is quite different from the original materials.

The distinctions between the original material—whole blood—and what emerges from the manufacturing activity—Source Plasma—are many:

1. Practically speaking, whole blood has almost none of the characteristics or uses to which Source Plasma can be put. Source Plasma, because it contains no formed living bodies, as does whole blood, can be stored indefinitely in its fresh, frozen state. Whole blood, on the other hand, must be used within twenty-one days of removal from the donor. Because of this distinction, whole blood is often in short supply.

2. Further, the minimum interval between whole blood donations is approximately two months, whereas donors may undergo plasmapheresis twice on a seven day period.

3. Source Plasma has no 'blood type' restrictions. As a result, it can be used in further drug manufacture for the treatment of patients irrespective of their blood type.

4. Source Plasma may be sterilized, whereas whole blood may not. This sterilization capability is key to the manufacture of certain pharmaceutical products.

5. Source Plasma contains a factor known as gamma globulin which in turn contains antibodies that prevent the spread of various infectious diseases such as whooping cough, tetanus, diphtheria, etc. Through hyper-immunizing certain donors with tetanus and pertussis vaccines, the petitioner is able to increase the amounts of antibodies within the donor's plasma, which plasma is then available to produce vaccines. Although these antibodies are present in whole blood, the concentration of them in plasma, plasma's adaptability and plasma's availability makes plasmapheresis vital to vaccine production.

6. Source Plasma also contains certain clotting factors, AHF – Factor 8, which although present in whole blood, are more efficient and effective when their use is made exclusive of other blood components. These clotting factors are useful in the treatment of hemophiliacs as well as in trauma or in surgery when clotting may be inhibited. To preserve this character of the product, the temperature must not rise above –20 degrees Centigrade.

7. The taxpayer's processing converts whole blood, which is essentially unusable by taxpayer's customers into a new article--Source Plasma—which can be utilized in further manufacturing processes by the taxpayer's customers.

8. The manufacture of Source Plasma transforms whole blood into an article which is used solely in further drug manufacturing by taxpayer's customers. The derivatives of Source Plasma are divided into three categories: coagulation products, immune globulins and plasma volume expanders. The coagulation products are used to treat patients with immune system disorders or patients who have been exposed to bacterial or viral infections; for example, tetanus immune globulin is used to treat an injured patient who has not had a tetanus immunization. The plasma volume expanders consists of serum albumin used to

increase a patient's plasma in cases of shock, post-burn therapy and protein loss following surgery. A concentrated form of albumen is used in cases of gastrointestinal, lever, and kidney diseases. Albumin is also used in heart surgery. The Source Plasma produced in this manufacturing operation is used to produce some 100 different medical products and drugs which can be used to treat all persons irrespective of their blood type. Accordingly, the adaptability and use of the substance manufactured, Source Plasma, is quite different from the original whole blood.

9. Source Plasma is not used for transfusions (as whole blood is), is not sent to hospitals and in fact, is not even approved for use in hospitals.

Through the plasmapheresis procedure, the taxpayer has created a distinct and new substance which is different in form than whole blood and contains qualities which give it adaptability to situations where the use of whole blood would be unsuitable.

The F.D.A. requires us to hold an Establishment License (Exhibit A – License #) and a Product License (Exhibit B - License #) which authorizes us to propagate or manufacture and prepare Source Plasma for sale.

Enclosed are formal rulings for the states of Pennsylvania, Indiana, Wisconsin and Arkansas, which is a determination on the same type of operations as being manufacturing and exempt form sales and use tax on supplies and testing used in the manufacturing process. (See Exhibits C, D, E, and F).

I have also enclosed a blank label that is placed on each unit of source plasma and a shipping label that is placed on each carton to be shipped. Please note: 'Caution: For Manufacturing Use Only'. (See Exhibits G and H).

In conclusion, the taxpayer states that the plasmapheresis activity is manufacturing because it results in a distinctly new product with a transformation in form, quality and adaptability in use quite different from the original whole blood. In addition, taxpayer notes that its activities are viewed as manufacturing by both the Federal government and by the Department of Health of Illinois. Thus, the taxpayer respectfully submits that it is engaged in manufacturing and is thereby entitled to the manufacturing exemption in determining sales and use tax on supplies and testing used in the manufacturing process.

Thank you for your time and consideration. Should you need additional information, please contact ####. Please correspond with me at ADDRESS

The Retailers' Occupation Tax Act, 35 ILCS 120/1 and following, imposes a tax upon persons engaged in this State in the business of selling tangible personal property to purchasers for use or consumption. The State rate of tax under the Retailers' Occupation Tax Act is 6.25% plus applicable local taxes.

Under the Retailers' Occupation Tax Act, the manufacturing machinery and equipment exemption extends to machinery and equipment that is used primarily (over 50% of the time) in the manufacturing or assembling of tangible personal property for wholesale or retail sale or lease. See the enclosed copy of 86 Ill. Adm. Code 130.330. As you will note at subsection (b)(1), the exemption

“exempts from tax only machinery and equipment used in manufacturing or assembling tangible personal property for sale or lease. Thus, the use of machinery and equipment in any industrial, commercial or business activity which may be distinguished from manufacturing or assembling will not be an exempt use and such machinery and equipment will be subject to tax.”

Subsection (b)(2) provides that “[t]he manufacturing process is the production of any article of tangible personal property, whether such article is a finished product or an article for use in the process of manufacturing or assembling a different article of tangible personal property, by procedures commonly regarded as manufacturing, processing, fabricating, or refining that changes some existing material or materials into a material with a different form, use, or name. These changes must result from the process in question and be substantial and significant.” The manufacturing machinery and equipment exemption also extends to repair and replacement parts as long as the parts are incorporated into machinery and equipment that is exempt under the regulation.

Subsection (d)(3)(C) provides that “[t]he use of machinery or equipment to inspect, test or measure the tangible personal property to be sold where such function is an integral part of the production flow” will generally be considered to constitute an exempt use. However, subsection (d)(4)(B) provides that “[t]he use of machinery or equipment in research and development of new products or production techniques, machinery, or equipment, will generally not be considered to be manufacturing.”

As you can see, subsection (c)(1) provides that “[t]he law exempts only the purchase and use of ‘machinery’ and ‘equipment’ used in manufacturing or assembling. Accordingly, no other type or kind of tangible personal property will qualify for the exemption, even though it may be used primarily in the manufacturing or assembling of tangible personal property for sale or lease. Subsections (c)(2) and (c)(3) set forth what is meant by “machinery” and “equipment.” Please note that subsection (c)(3) provides that the exemption does not extend to supplies, such as needles and bags.

Machinery and equipment used primarily in the manufacturing of such products as Source Plasma for wholesale or retail sale can qualify for the manufacturing machinery and equipment exemption from sales tax.

I hope this information is helpful. The Department of Revenue maintains a Web site, which can be accessed at www.revenue.state.il.us. If you have further questions related to the Illinois sales tax laws, please contact the Department's Taxpayer Information Division at (217) 782-3336.

If you are not under audit and you wish to obtain a binding Private Letter Ruling regarding your factual situation, please submit all of the information set out in items 1 through 8 of the enclosed copy of Section 1200.110(b).

Very truly yours,

Martha P. Mote
Associate Counsel

MPM:msk
Enc.